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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-03-33

June 5, 2003

Mr. Robert E. Martin, President/Owner
Bobarosa's Gourmet Inc.
22151 U.S. Highway 19 North
Clearwater, Florida 33765

Dear Mr. Martin:

On January 3, 7, and 13, 2003, the Food and Drug Administration (FDA) conducted an inspection of your food processing plant located at 22151 U.S. Highway 19 North Clearwater, Florida. This inspection revealed that you manufacture acidified foods at this facility, including but not limited to: Pickled Garlic and Thai Peanut Dip.

As a manufacturer of acidified food products, you are required to comply with both the Federal Food, Drug, and Cosmetic Act (the Act) and the federal regulations relating to the processing of acidified food products. These regulations are described in Title 21, Code of Federal Regulations Part 108, Emergency Permit Control (21 CFR 108), and Part 114, Acidified Foods (21 CFR 114). The Emergency Permit Control Regulation issued under Section 404 of the Act, allows FDA to control the manufacture of acidified foods by emergency permit only, if violative conditions exist. You can find this Act and the Emergency Permit Control and Acidified Foods regulations through links in FDA's home page at http://www.fda.gov . The Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food Regulation is in 21 CFR Part 110.

During our inspection, our investigator documented deviations from the Act and the regulations relating to the processing of acidified foods, specifically the Emergency Permit Control regulations found in 21 CFR 108, the Acidified Food regulations found in 21 CFR 114, and the Good Manufacturing Practice regulations found in 21 CFR 110. These deviations cause your acidified food products to be adulterated and in violation of section 402(a)(4) of the Act, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health. At the conclusion of the inspection, FDA presented you with an FDA Form 483, listing deviations found during the inspection.

The deviations of concern are as follows:

- Your firm failed to submit information on your firm's scheduled processes for all its acidified food products (various pickled garlic products and Thai peanut dip) on Form FDA 2541a [21 CFR 108.25(c)(2)]. We note that when your firm submitted its registration (Form FDA 2541) your firm erroneously described your firm's products as low-acid foods instead of as acidified foods. We also note that your firm erroneously requested incorrect forms on which to file scheduled process information. Your firm requested Form FDA 2541c (used for aseptically processed low-acid foods); however, the regulations require the use of Form FDA 2541a for filing scheduled process information for acidified foods. We also note filing forms (Form FDA 2541c) submitted by your firm dated 5-02-02 were returned to your firm on July 17, 2002, advising your firm to resubmit the scheduled process information using the correct forms (Form FDA 2541a). As of this date, review of FDA's files reveals there is no record that your firm has resubmitted the required information using the correct forms. We strongly recommend that you read, and follow, the instructions for correctly executing scheduled process filing as required by 21 CFR 108.25(c)(2). If you are in doubt about what information is required or have questions regarding the procedures, we strongly encourage your firm to seek the services of a consultant familiar with FDA rules and regulations regarding the processing of acidified foods.

- Your firm failed to have all plant personnel involved in acidification, pH control, heat treatment, or other critical factors of the operation under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in food handling techniques, food protection principles, personnel hygiene, plant sanitation practices, pH controls, and critical factors in acidification, and who has satisfactorily completed the required course of instruction [21 CFR 108.25(f) and 114.10].

- Your firm failed to have scheduled processes for acidified products established by qualified persons having expert knowledge of acidification and processing of acidified foods [21 CFR 114.83].

- Your firm failed to prepare processing and production records showing adherence to scheduled process, including records of pH measurements and other critical factors intended to ensure a safe product, and containing sufficient additional information such as product code, to permit a public health hazard evaluation of the processes applied to each lot, batch, or other portion of production [21 CFR 108.25(g) and 114.100 (b)]. Specifically, your firm failed to record finished equilibrium pH values for [redacted] pickled garlic batches manufactured on October 4, 2002, and again on December 12, 2002. In addition, processing records examined by our investigator from January 1, 2002, to January 1, 2003, revealed that your firm was not always recording manufacturing codes and container closure examinations. Specifically, our investigator reported that [redacted] batches of products did not contain manufacturing codes or the codes documented on batch records were incorrect or

incomplete, and no closure examinations were recorded for [redacted] batches during this same time period.

- Your firm failed to mark each container or product with an identifying code permanently visible to the naked eye with identification specifying in code the establishment where the product was packed, the product contained therein, and the year, day, and period packed [21 CFR 114.80(b)]. Our investigator reported that your firm does not code 5-gallon pails or private label containers, except your firm marks the date of processing on both pails and cases of un-coded product.

- Your firm has not prepared and does not maintain files on a current procedure for use for products under your firm's control, which ask the distributor to follow, including plans for recalling products that may be injurious to health; for identifying, collecting, warehousing, and controlling products; for determining the effectiveness of recalls; for notifying the FDA of any recalls; and for implementing recall programs [21 CFR 108.25(e) and 114.100(d)]. Our investigator reported that your firm does not have a recall plan and that your firm's records do not indicate distribution unless the product is for private label customer/distribution.

We also reviewed your firm's labels for your firm's pickled garlic products and have determined that Bobarosa's Pickled Garlic, Italian Style, Roasted Red Pepper, Original, Greek Style, Spicy, Cajun Style, and Jalapeno Pepper are misbranded within the meaning of section 403(r)(1)(B) of the Act in that the labels bear the health claims "Garlic helps improve cholesterol" in a heart vignette and "... proven to cut cholesterol..." which have not be authorized for conventional foods at this time.

This letter is not intended to be an all-inclusive list of deficiencies at your facility and we remind you that it is your responsibility to ensure that you operate your processing facility in compliance with the Act, the mandatory requirements of Emergency Permit Control (21 CFR Part 108), and the good manufacturing practices (21 CFR Parts 110 and 114) as applicable.

We communicated to you many of the same significant deviations as a result of our inspection conducted on November 13, 2001. Our January 2003 inspection showed few corrections.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include seizure, or issuance of an Order of Need To Obtain and Hold a Temporary Emergency Permit.

Please notify this office in writing of any steps you have taken to correct the noted violations, and the timeframe within which the corrections will be completed. Corrective actions should also indicate the person responsible for effecting correction, and include any supporting documentation indicating correction has been achieved.

Please send your reply to Diane J. Englund, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

For your information, our investigator collected a sample of pickled garlic (FDA Sample No. 200913) during this inspection. Examination of twelve jars of the product revealed a pH range of 3.60 to 3.85. Our investigator also collected a sample of peanut dip (FDA Sample

No. 200912) during this inspection. Examination of twelve jars of the product revealed pH values greater than 4.6.

Sincerely,

Emma Singleton
Director, Florida District